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AMENDMENT

APPENDIX: Clean copy of pages of specification as amended

ATL1 #5G1322 v1

approximately 7% of the total body weight) is processed over a period of approximately 2 ½ hours. The filtrate is then returned from the filtration device to the patient at the second site. Standard microprocessor controls can be used to regulate the blood flow, for example, by monitoring the volume of the blood products being removed, in combination with flow rate monitors and pump speed.

- The entire system should first be flushed with saline and then treated with an anticoagulant or ant clotting agent, such as sodium heparin, to be sure that there are no locations within the system where blood clotting can occur.
- 10 Moreover, small amounts of anticoagulants should be continually introduced into the blood stream directed to the ultrafilter to ensure than no clotting occurs during the filtration process. All of the surfaces of the system which come in contact with the blood and fluids which are infused into the patient must be sterilized prior to commencing treatment.
- 15 Figure 1 illustrates a system for ultrapheresis. Blood is removed from a patient by means of a venous catheter 10 with the distal lead 11 thereof disposed in the superior vena cava 12 leading to the patient's heart 13. The blood passes through conduit 14 to a drip chamber 15 and then into pump 16 which controls the pressure of the blood to the separation unit 17, preferably an ultrafilter as shown, through conduit 18. A pressure gauge 19 is provided on conduit 14 to continually monitor arterial pressure. A syringe pump 20 feeds an anti-clotting drug such as sodium heparin to conduit 18 to prevent the clotting of blood in the ultrafilter 17. In the ultrafilter 17 the blood stream passes over the ultrafilter medium or membrane or absorbent column 21 under pressure. The blood fraction including the low molecular weight components passes through the membrane or absorbant column 21 and is discharged as permeate through conduit 22. The retentate or treated blood containing the high molecular weight components, which include whole blood cells and platelets, is discharged into conduit 23 which ultimately leads back to

the patient. Volumetric pump 27 passes a controlled amount of permeate to a container 28 for containment and for measuring. Volumetric pump 30, which is preferably the same type and capacity as pump 27, pumps replacement fluid from a container 31 to conduit 32, which directs the fluid to conduit 23 where it mixes with the retentate or treated blood. The treated blood and other components are returned to the patient through venous catheter 34, the distal or discharge end of which is disposed in the brachiocephalic vein. The volumetric pumps 27 and 30 are preferably set either to pump the same total amount of fluid or to pump at the same rate, so that the same volume of fluid which is removed from the patient's blood stream as permeate is returned as replacement fluid. The blood stream in conduit 23 is passed through filter 36 to remove clots or other debris from the blood stream. A drip chamber 37 ensures that no significant quantities of air enter the patient's blood stream. A venous pressure gauge 38 is provided to continually monitor venous blood pressure.

Figure 2 illustrates another embodiment wherein blood removed from a patient is first passed through conduit 30 to a first ultrafilter 31 to selectively separate a blood fraction with components having molecular weights less than about 1,000,000 Daltons. The retentate from this ultrafiltration which contains the high molecular weight components is returned through conduit 32 to the patient. The permeate from the first ultrafilter 30 is passed through conduit 33 to a second ultrafilter 34 where a blood fraction having a molecular weight below 30,000 is removed from the permeate stream from the first ultrafilter 30. The permeate from the second ultrafilter 34, which contains the very low molecular weight components such as salts and nutrients may be returned to the patient through conduit 35. The retentate from the second ultrafilter which contains blocking factors, IgG immunoglobulins and other components is discharged through conduit 36 and 13.